K122664

510(k) Summary

APR 3 0 2013

Date:	30 August 2012
Sponsor:	Zuga Medical Inc. 1163 East 40th Street, Suite 202 Cleveland, OH 44114 Phone: 216.292.5910 Facsimile: 216.292.5911
Contact Person:	Chan Wang, CEO
Trade Names:	Zuga™ Dental Implant System
Device Classification	Class II
Classification Names:	Implant, endosseous, root-form & Abutment, implant, dental, endosseous
Regulation:	872.3640
Device Product Codes:	DZE & NHA
Device Description:	The Zuga™ Dental Implant System includes endosseous dental implants, sealing caps, gum shapers, dental implant abutments and fixation screws in a variety of sizes to accommodate differing patient anatomy. Implantation is suitable for one- or two-stage procedures. Endosseous implants are bone level, self-tapping, root-form, threaded. The threaded surface is aluminum oxide (Al_2O_3) blasted then passivated. These are offered in diameters from 3.5 to 5.5mm in diameter with lengths ranging from 8mm to 17mm. Size-matched anterior and posterior abutments are offered having post heights from 4.0 to 7.0mm. These are fastened to the implant using a fixation screw. Sealing caps and gum shapers provide protection to the abutment connection threads during endosseous and gingival healing. The implants are provided sterile, the remaining components must be sterilized prior to use.
Indications for Use:	The Zuga Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges and overdentures. The Zuga Dental Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Materials:	The Zuga™ Dental Implant System components including implant, abutments, sealing caps and gum shapers are manufactured from titanium (Grade 4) as described by ASTM F67. The Zuga™ Dental Implant System fixation screw is manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.
Predicate Devices:	Reliadent Dental Implant System (K043428 and K061323) Biomet 3i Certain® System (K100724) KAT System (K083544 and K101201) Southern Implants (K070841, K071161)

Technological Characteristics: The fundamental scientific technology of the Zuga™ system is the same as previously cleared devices as shown below, i.e., each of the Zuga design features is common to one or more of the predicates.

System:	**Zuga**	**Reliadent**	**Biomet 3i**	**KAT**	**Southern Implants**
Material of manufacture:	Titanium	Titanium	Titanium, Titanium alloy	Titanium alloy	Titanium
Design:					
Endosseous implant	Root-form, Straight	Root-form, Straight	Root-form, Straight and tapered	Root-form, Straight and tapered	Root-form, Straight and tapered
Method of stabilization	Threaded fixation	Threaded fixation	Threaded fixation	Threaded fixation	Threaded fixation
Range of Diameters	3.5 – 5.5mm	3.0 – 5.5mm	3.25 – 6mm	2.5 – 8mm	—
Range of Lengths	8 – 17mm	8 – 16mm	8.5 – 20mm	6 – 14mm	—
Surface treatment	Yes, Al_2O_3 blasted, passivated	Yes, Titanium blasted and acid etched	Yes, acid etched	Yes, Al_2O_3 blasted, passivated	Yes, Al_2O_3 blasted
Color-coding	Seating surface	Anodized seating	Seating surface	None	None
Sterilization	Sterile, gamma radiation	Sterile, gamma radiation	Sterile, gamma radiation	Sterile, radiation	Sterile, gamma radiation
Abutments	Standard	Standard, angled	—	Standard, angled	Standard, angled
Sterilization	Non-sterile	Non-sterile	—	Non-sterile	—
Connection to implant	Hex alignment, screw attachment	Hex alignment, screw attachment	—	Indexing key alignment, 1.5° locking taper, screw attachment	—
Color-coding	Connection interface	Connection interface	—	—	—

Performance Data: Pre-clinical testing of the Zuga™ Dental Implant System included:

- Mechanical testing per ISO 14801
- Cytotoxicity testing per ISO 10993-5
- Surface analysis by FTIR & SEM-EDS

No clinical data was used in support of this submission.

Conclusion: The Zuga™ Dental Implant System devices possess the same intended use and technological characteristics as the predicate devices. This with the information provided in the submission permit the conclusion that the Zuga™ Dental Implant System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 30, 2013

Zuga Medical, Incorporated
C/O Karen E. Warden, PhD
President
BackRoads Consulting, Incorporated
P.O. Box 566
CHESTERLAND OH 44026-2141

Re: K122664
Trade/Device Name: Zuga™ Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 16, 2013
Received: April 18, 2013

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122664

Indications for Use Statement

510(k) Number: **K122664**

Device Name: **Zuga™ Dental Implant System**

Indications for Use:

The Zuga Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges and overdentures. The Zuga Dental Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=1300087950
Date: 2013.04.29 15:57:18 -04'00'

Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122664